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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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04/13/2001

Arthur Lander

82351.0003

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34284

7590

04/18/2007

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EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1643

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/18/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/807,575	<b>Applicant(s)</b> LANDER ET AL.	
	<b>Examiner</b> Alana M. Harris, Ph.D.	<b>Art Unit</b> 1643	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 January 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 7-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 17 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Claims 1-18 are pending.

Claims 1 and 5 have been amended.

Claims 7-16, drawn to non-elected inventions are withdrawn from examination.

Claims 1-6, 17 and 18 are examined on the merits to the extent the binding molecule bind to glypican-1.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Rejections***

#### ***Claim Rejections - 35 USC § 112***

3. The rejection of claims 1-6, 17 and 18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn. Applicants have amended the claim to longer recite the indefinite recitation "and *an* information".

***Maintained Grounds of Rejection and New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-6, 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

Applicants have amended claims to include “an instruction that provides information that binding of the binding molecule to a cell is indicative of a human cancer cell that overexpresses glypican-1”, see claim 1. Applicants also have the recitations, diagnostic kit and therapeutic kit in claims 1, 5, 17 and 18. Applicants do not have support for the binding molecule comprised in any type kit, nor do Applicants have support for instructions that provide information regarding the binding molecule. Applicants' original claims read on a diagnostic agent and a composition comprising a therapeutic agent, but these recitations do not provide support for kits comprising said agents. After a cursory review of the specification the Examiner does not note where in the specification contemplation for this claim language. Applicants have not pointed the Examiner's attention to any place in the specification by page and line where support

Art Unit: 1643

can be found for these contemplations. Applicants should direct the Examiner's attention to support for the claim language or delete the new matter.

6. Claims 2-4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 2-4 recite "[t]he diagnostic agent...". Claim 1 lacks antecedent bases for the recitation. Likewise, claim 5 lacks antecedent bases for the recitation "[t]he composition" as cited in claim 6.

***Claim Rejections - 35 USC § 102***

7. The rejection of claims 1-6, 17 and 18 under 35 U.S.C. 102(b) as being anticipated by Birembaut et al. (Journal of Pathology 145: 283-296, April 1985) is maintained.

Applicants assert the term, heparin sulfate proteoglycans (HSP) denotes a class of diverse molecules, see Remarks, page 5, 3<sup>rd</sup> paragraph. And Birembaut teaches the loss of regular arrangement of various basement membrane components and not the presence or absence of HSP. These points of view and arguments have been carefully considered, but found unpersuasive.

As presented in the FAOM mailed October 25, 2006 glypicans (before the filing date) are art known to be the same as HSP, see Edgren et al. Glycobiology 7(1): 103-112, 1997 and Fransson et al. The International Journal of Biochemistry and Cell

Art Unit: 1643

Biology 35: 125-129, 2003. And while Birembaut does teach the loss of regular arrangement of various basement membrane components, this assessment in and of itself reads on detection as set forth in the instant claims. Determining the loss of basement membrane components does not teach away from detection of glypican. Accordingly, the rejection is maintained for the reasons of record.

8. The rejection of claims 1-6 under 35 U.S.C. 102(b) as being anticipated by Karthikeyan et al. (Journal of Cell Science 107: 3213-3222, November 1994), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998) is maintained.

Applicants submit "...Karthikeyan teaches rat anti-glypican-1 antibodies and that Kleef teaches that the rat anti-glypican-1 antibody also recognizes human glypican- 1", but argue "reliance on the preamble during prosecution would transform the preamble into a claim limitation.", see page 6 of the Remarks, paragraphs 1 and 3. Applicants aver instruction is not inherently present in the reference and the USPTO has issued numerous patents with instructions. Applicants' arguments and points of view have been carefully considered, but found unpersuasive.

Applicants' attention is directed to MPEP 2106.01 and 2112.01, wherein it is noted "the USPTO personnel need not give patentable weight to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate" and "[w]here the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the

Art Unit: 1643

content of the printed matter will not distinguish the claimed product from the prior art", respectively, see *In re Ngai*, \*\*>367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004). Consequently, the instant rejection is still of merit and the rejection is maintained for the reasons of record.

9. The rejection of claims 1-6 under 35 U.S.C. 102(b) as being anticipated by Ivins et al. (Developmental Biology 184: 320-332, April 15, 1997), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998) is maintained.

Applicants' arguments are essentially the same as those provided against the Karthikeyan reference. These points of view have been carefully considered, but found unpersuasive.

The Examiner's response to the instant rejection is essentially the same as that stated in response to the Karthikeyan reference and the rejection is maintained for the reasons of record.

10. The rejection of claims 1-6 under 35 U.S.C. 102(a) as being anticipated by Liang et al. (The Journal of Cell Biology 139(4): 851-864, November 17, 1997), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998) is maintained.

Applicants' arguments are essentially the same as those provided against the Karthikeyan reference. These points of view have been carefully considered, but found unpersuasive.

Art Unit: 1643

The Examiner's response to the instant rejection is essentially the same as that stated in response to the Karthikeyan reference and the rejection is maintained for the reasons of record.

11. The rejection of claims 1-6 under 35 U.S.C. 102(a) as being anticipated by Litwack et al. (Developmental Dynamics 211: 72-87, January 1998), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998) is maintained.

Applicants' arguments are essentially the same as those provided against the Karthikeyan reference. These points of view have been carefully considered, but found unpersuasive.

The Examiner's response to the instant rejection is essentially the same as that stated in response to the Karthikeyan reference and the rejection is maintained for the reasons of record.

12. The rejection of claims 1-6 under 35 U.S.C. 102(a) as being anticipated by Liu et al. (The Journal of Biological Chemistry 273(35): 22825-22832, August 28, 1998), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998) is maintained.

Applicants' arguments are essentially the same as those provided against the Karthikeyan reference. These points of view have been carefully considered, but found unpersuasive.



Art Unit: 1643

The Examiner's response to the instant rejection is essentially the same as that stated in response to the Karthikeyan reference and the rejection is maintained for the reasons of record.

***Claim Rejections - 35 USC § 103***

13. The rejection of claims 1-6, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karthikeyan et al. (Journal of Cell Science 107: 3213-3222, November 1994), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998), and in view of Birembaut et al. (Journal of Pathology 145: 283-296, April 1985) is maintained.

Applicants' arguments for the instant rejection are the same as those stated in response to the 102 rejections. Furthermore, Applicants aver Birembaut teach HSP in healthy cells, which is counter to the claimed subject matter and Birembaut in combination with Karthikeyan do not render the claims obvious. These arguments and points of view have been carefully considered, but found unpersuasive.

The instant rejection is maintained because the primary reference is still of consequence, as well as the secondary reference, Birembaut. The combination of the cited references renders the claims *prima facie* obvious as noted in the rejection presented in the FAOM, see page 10, section 14.

14. The rejection of claims 1-6, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivins et al. (Developmental Biology 184: 320-332, April 15,

Art Unit: 1643

1997), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998), and in view of Birembaut et al. (Journal of Pathology 145: 283-296, April 1985) is maintained.

Applicants' arguments for the instant rejection are the same as those stated in response to the 102 rejections. Furthermore, Applicants aver Birembaut teach HSP in healthy cells, which is counter to the claimed subject matter and Birembaut in combination with Ivins do not render the claims obvious. These arguments and points of view have been carefully considered, but found unpersuasive.

The instant rejection is maintained because the primary reference is still of consequence, as well as the secondary reference, Birembaut. The combination of the cited references renders the claims *prima facie* obvious as noted in the rejection presented in the FAOM, see page 10, section 15.

15. The rejection of claims 1-6, 17 and 18 under 35 U.S.C. 103(a) as being unpatentable over Liang et al. (The Journal of Cell Biology 139(4): 851-864, November 17, 1997), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998), and in view of Birembaut et al. (Journal of Pathology 145: 283-296, April 1985) is maintained.

Applicants' arguments for the instant rejection are the same as those stated in response to the 102 rejections. Furthermore, Applicants aver Birembaut teach HSP in healthy cells, which is counter to the claimed subject matter and Birembaut in

Art Unit: 1643

combination with Liang do not render the claims obvious. These arguments and points of view have been carefully considered, but found unpersuasive.

The instant rejection is maintained because the primary reference is still of consequence, as well as the secondary reference, Birembaut. The combination of the cited references renders the claims *prima facie* obvious as noted in the rejection presented in the FAOM, see page 11, section 16.

16. The rejection of claims 1-6, 17 and 18 under 35 U.S.C. 103(a) as being unpatentable over Litwack et al. (Developmental Dynamics 211: 72-87, January 1998), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998), and in view of Birembaut et al. (Journal of Pathology 145: 283-296, April 1985) is maintained.

Applicants' arguments for the instant rejection are the same as those stated in response to the 102 rejections. Furthermore, Applicants aver Birembaut teach HSP in healthy cells, which is counter to the claimed subject matter and Birembaut in combination with Litwack do not render the claims obvious. These arguments and points of view have been carefully considered, but found unpersuasive.

The instant rejection is maintained because the primary reference is still of consequence, as well as the secondary reference, Birembaut. The combination of the cited references renders the claims *prima facie* obvious as noted in the rejection presented in the FAOM, see page 12, section 17.

Art Unit: 1643

17. The rejection of claims 1-6, 17 and 18 under 35 U.S.C. 103(a) as being unpatentable over Liu et al. (The Journal of Biological Chemistry 273(35): 22825-22832, August 28, 1998), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998), and in view of Birembaut et al. (Journal of Pathology 145: 283-296, April 1985) is maintained.

Applicants' arguments for the instant rejection are the same as those stated in response to the 102 rejections. Furthermore, Applicants aver Birembaut teach HSP in healthy cells, which is counter to the claimed subject matter and Birembaut in combination with Liu do not render the claims obvious. These arguments and points of view have been carefully considered, but found unpersuasive.

The instant rejection is maintained because the primary reference is still of consequence, as well as the secondary reference, Birembaut. The combination of the cited references renders the claims *prima facie* obvious as noted in the rejection presented in the FAOM, see page 13, section 18.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone

Art Unit: 1643

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**ALANA M. HARRIS, PH.D.**

**PRIMARY EXAMINER**

  
Alana M. Harris, Ph.D.

10 April 2007